K082120

OCT 24 2008

Summary of Safety and Effectiveness information

510(k) Premarket Notification – Aequalis Reversed Fracture Shoulder Prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***AEQUALIS Reversed Fracture Shoulder Prosthesis***
Common name:	Total-Shoulder System and Hemi-Shoulder System
Classification name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mr Damien Guillaud
Regulatory affairs Specialist
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: 00 33 4 76 61 35 00
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e-mail : damien.guillaud@tornier.fr

4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS

5) Equivalent / Predicate device

Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941, K041873, K050316, K061439.
Aequalis Fracture Shoulder System, TORNIER SA, K994392, K003728, K032679, K043077, K060209.
Delta Xtend Reverse Shoulder System, DEPUY, K062250, K071379.
Delta Shoulder, DEPUY, K021478
Aequalis Reversed Adapter, TORNIER SA, K071948

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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

6) Device description

The *Aequalis Reversed Fracture Shoulder Prosthesis* is intended to be used to relieve pain or significant disability following massive cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Fracture Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm and its *Aequalis Fracture Shoulder* humeral stem-like design allows to facilitate the bone reconstruction and improve the tuberosity healing and fixation.
The *Aequalis Reversed Fracture Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

7) Materials

The humeral component, the base of the glenoid implant and the screw of the glenoid sphere are manufactured from Titanium alloy.

The metaphyseal plug, the humeral spacer, the tightening screw for humeral spacer, the hemi-prosthesis adaptor, the adaptor union screw and the glenoid sphere are manufactured from Cobalt-Chromium alloy.

The hydroxylapatite coating conforms to the ASTM standard F 1185. The coating is performed by BioCoat, Inc. according to their Master File MAF-339.

Metaphyseal inserts are made of ultra-high molecular weight polyethylene (UHMWPE).

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8) Indications

The *Aequalis Reversed Fracture Shoulder Prosthesis* is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain or significant disability following arthropathy associated to a grossly deficient rotator cuff joint :

- in case of traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures, or
- in case of bone defect in proximal humerus.

The *Aequalis Reversed Fracture Shoulder Prosthesis* is also indicated for prosthetic revisions with a grossly deficient rotator cuff joint when other treatments or devices have failed.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemiprosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the *Aequalis Reversed Fracture Shoulder Prosthesis* into a non reversed hemi-prosthesis.

When, in case of revision of a *Aequalis Reversed Fracture Shoulder* humeral stem, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of *Aequalis Reversed* range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the *Aequalis Reversed Fracture Shoulder Prosthesis* into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

The *Aequalis Reversed Fracture Shoulder* humeral stem is used in association with the glenoid components of the *Aequalis Reversed Shoulder Prosthesis*.

The *Aequalis Reversed Fracture Shoulder* humeral stem is for cemented use only.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Tornier
% Mr. Damien Guillaud
Regulatory Affairs Specialist
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38334 Saint Ismier Cedex
France

OCT 2 4 2008

Re: K082120
Trade/Device Name: Aequalis Reversed Fracture Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: July 24, 2008
Received: July 28, 2008

Dear Mr. Guillaud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082120

Device Name: *Aequalis Reversed Fracture Shoulder Prosthesis*

Indications For Use:

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Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K082120